plexed p24 antigen may not be detected in a sandwich immunoassay like that described here. Because the current p24 antigen assay in this example does not involve decomplexation, p24 antigen may not be detectable when it is bound by anti-p24 antibody present in the sample. The decomplexation methods described above may be applied to expose the antigen and make it detectable by the disclosed assays.

[0214] Of the 10 HIV-1 positive samples with indeterminate Western Blot results, the HIV-1 antibody assay gave five positive, two indeterminate, and three negative results. All of these samples are "true positive" for HIV infection as defined by the presence of viral RNA. These results suggest that the antibody assay disclosed herein has superior sensitivity relative to the Western Blot reference method. Of the 10 HIV-1 positive samples with weak positive Western Blot results, the HIV-1 assay of the present embodiment was positive for all 10.

[0215] In summary, the combined HIV-1 antigen/antibody assay demonstrated here has superior sensitivity to the Western Blot reference method. This includes detection of some samples in the pre-seroconversion window phase. We note that in this example, each sample was run in two separate cartridge channels, one for antigen and one for antibody. By combining the sandwich assay approach demonstrated in Examples 9 and 10 with the sandwich immunoassay described in this Example, a single fluidic channel, antigen/antibody combination assay may also be performed. It is to be noted that the antigen-antibody assay may also be modified to detect infections by other agents, for example, HCV and syphilis, among others.

Additional Embodiments

[0216] In certain applications, such as when more than one addition of a fluid into the assay cartridge is required, it may be advantageous to place the assay cartridge at a tilt so as to assist with the fluid flow, such as discussed in previously-mentioned U.S. Provisional Patent Application Ser. No. 61/391,911. FIGS. **45** and **46** show a perspective view and a side view of a cartridge **4500**, which is a slight modification of cartridge **300** of FIGS. **3-11**. Cartridge **4500** includes an upper piece **4510** and a lower piece **4512**. Upper piece **4510** includes an inlet port **4528**, which is located at a distal end from textured grooves **344**, in contrast to cartridge **300**. Lower piece **4512** additionally includes fin features **4550**. As better visible in FIG. **46**, fin features **4550** includes a first portion **4552** and a second portion **4554**. First and second portions **4552** and **4554**, respectively, are configured such that, when cartridge **4500** is resting on first portion **4552**, then flow plate **324** (not visible) inside cartridge **4500** lies parallel to the resting surface (i.e., flat). When cartridge **4500** is resting on second portion **4554**, then flow plate **324** within cartridge **4500** lies at a 5-degree angle with respect to the resting surface such that inlet port **4528** is slightly elevated with respect to the outlet port of the flow plate (not visible). The angle of induced tilt may be any angle appropriate for optimum flow of the particular liquids being used in the assay. Optionally, the position of the inlet port and the direction of the tilt may be reversed, i.e., the inlet port may be located near textured grooves **344**, and the cartridge may be tilted such that the end with the textured grooves rests higher than a distal end away from the textured grooves.

[0217] In another embodiment, the reader instrument and cartridges may be accompanied by a rack. The purpose of the rack may be to help organize operator workspace. In another embodiment, the rack may be designed such that the cartridges, when placed on the rack, lies at a tilt in order to facilitate fluid flow through the cartridges. FIGS. **47-49** illustrate a tilt rack and cartridge system for facilitating batch processing of cartridges as well as the placement of the cartridges at a specified tilt angle.

[0218] FIG. **47** shows a tilt rack **4700**, including a plurality of slots **4720** into which cartridges may be placed. Each one of slots **4720** includes an indentation **4730** and notches **4735** configured for unidirectional placement of a compatible cartridge. Tilt rack **4700** may optionally include numbers **4740** for identifying slots **4720**. One side of tilt rack **4700** is designed to be higher than an opposing end such that the top surface of tilt rack **4700** is at an angle **4752** with respect to the surface on which the tilt rack rests. Angle **4752** may be, for example, 5 degrees or any suitable angle to optimize the fluid flow for the particular assay being run. Tilt rack **4700** may be, for example, molded out of a plastic or metal material, which may be readily cleaned with conventional detergents and cleaners.

[0219] FIG. **48** shows a cartridge **4800** which is configured to be compatible with tilt rack **4700**. Cartridge **4800** includes an upper piece **4810** and a lower piece **4812** with textured grooves **4814** to facilitate gripping. Although not visible in the figure, a waveguide and a mechanism for defining a fluidic channel, such as a gasket, are housed within cartridge **4800**, in accordance with an embodiment. An input port **4828** provides sample access to the fluidic channel defined within cartridge **4800**. Cartridge **4800** is sized and shaped so as to fit into one of slots **4720** of tilt rack **4710**, with protrusions **4860** on cartridge **4800** being designed to engage with notches **4735** of tilt rack **4700**. FIG. **49** shows an example of rack **4700** filled with eight cartridges **4800**.

[0220] In another embodiment, the rack may include one or more integrated timers (e.g., stopwatches) for user convenience. In another embodiment the rack may have buttons or other user interface means use for initiating timed steps. In another embodiment, the rack may have indicating means such as lights or alarms that provide feedback to the user. For example, insertion of a cartridge into the rack may initialize an internal timer. Upon completion of a pre-determined amount of time, a light may illuminate (or go out) and/or an audible chime may indicate to the user that a step has been completed. Multiple lights or indicating means could be used to stage multiple steps. In another embodiment, the rack may physically actuate features of the cartridge. For example, a physical actuator in the rack may deploy an on-cartridge reagent contained in a pre-loaded blister pack.

[0221] We note that the above embodiments are described in terms of labeled antigen assays. The sandwich assay concept described here, however, is not restricted only to labeled antigen assays. The sandwich assay approach and detection system described herein may be used, for example, with nucleic acid (e.g., DNA, RNA) based assays and cell-based assays.

[0222] The assay system described above may be provided in a kit. For example, a functional kit may include a reader instrument, one or more cartridges, a tilt rack, one or more sample mixing tubes, sample diluent solution, wash solution and fluorescent conjugate solution (such as anti-human IgG labeled with an appropriate dye, such as Dylight647 or Alexa649). The cartridges may be sealed in individual pouches for protection during shipping and storage. The reader instrument in the kit may include an on-board com-